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Altmann et al.

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(54) **BASKET CATHETER WITH MICROELECTRODE ARRAY DISTAL TIP**

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A61M 25/09	(2006.01)
A61B 18/00	(2006.01)
A61B 17/00	(2006.01)
A61B 19/00	(2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/6858*** (2013.01); ***A61B 5/0422*** (2013.01); ***A61B 18/1492*** (2013.01); ***A61M 25/0147*** (2013.01); ***A61M 25/09*** (2013.01); *A61B 2017/00053* (2013.01); *A61B 2018/00351* (2013.01); *A61B 2018/00357* (2013.01); *A61B 2018/00577* (2013.01); *A61B 2018/1465* (2013.01); *A61B 2018/1467* (2013.01); *A61B 2019/5251* (2013.01); *A61B 2019/5454* (2013.01); *A61M 2025/0177* (2013.01)

(58) **Field of Classification Search**
CPC .. A61B 5/0422; A61B 5/6858; A61B 5/6859; A61B 2018/00267
USPC 600/374; 606/41
See application file for complete search history.

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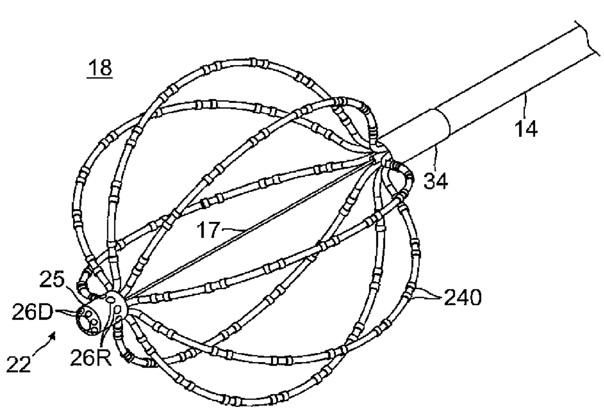
(74) *Attorney, Agent, or Firm* — Lewis Roca Rothgerber Christie LLP

(57) **ABSTRACT**

A catheter adapted for greater mapping resolution and location precision has a basket-shaped, high density electrode assembly for large-area mapping, and an integrated distal tip providing an array of ultra-high density microelectrodes for acute focal mapping. The basket-shaped electrode assembly **18** has a plurality of electrode-carrying spines and the distal tip has a nonmetallic, electrically insulating substrate body with indentations in which microelectrodes are positioned in a manner that the outer surface is generally flush with the outer surface of the substrate body to present a generally smooth, atraumatic distal tip profile.

20 Claims, 12 Drawing Sheets



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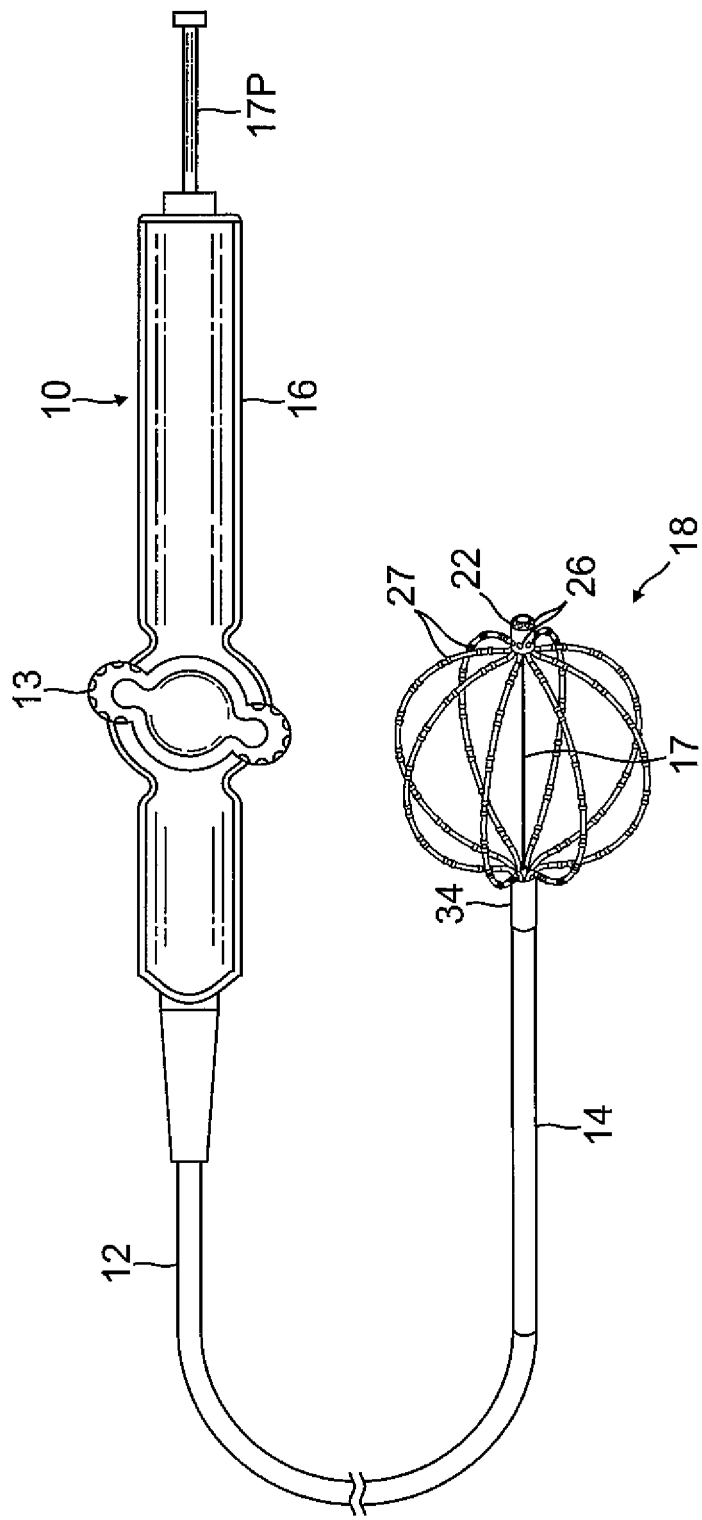


FIG. 1

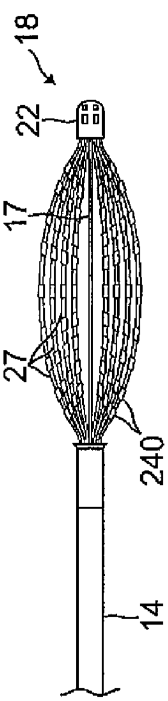

18
22
17
27
240
14

FIG. 2

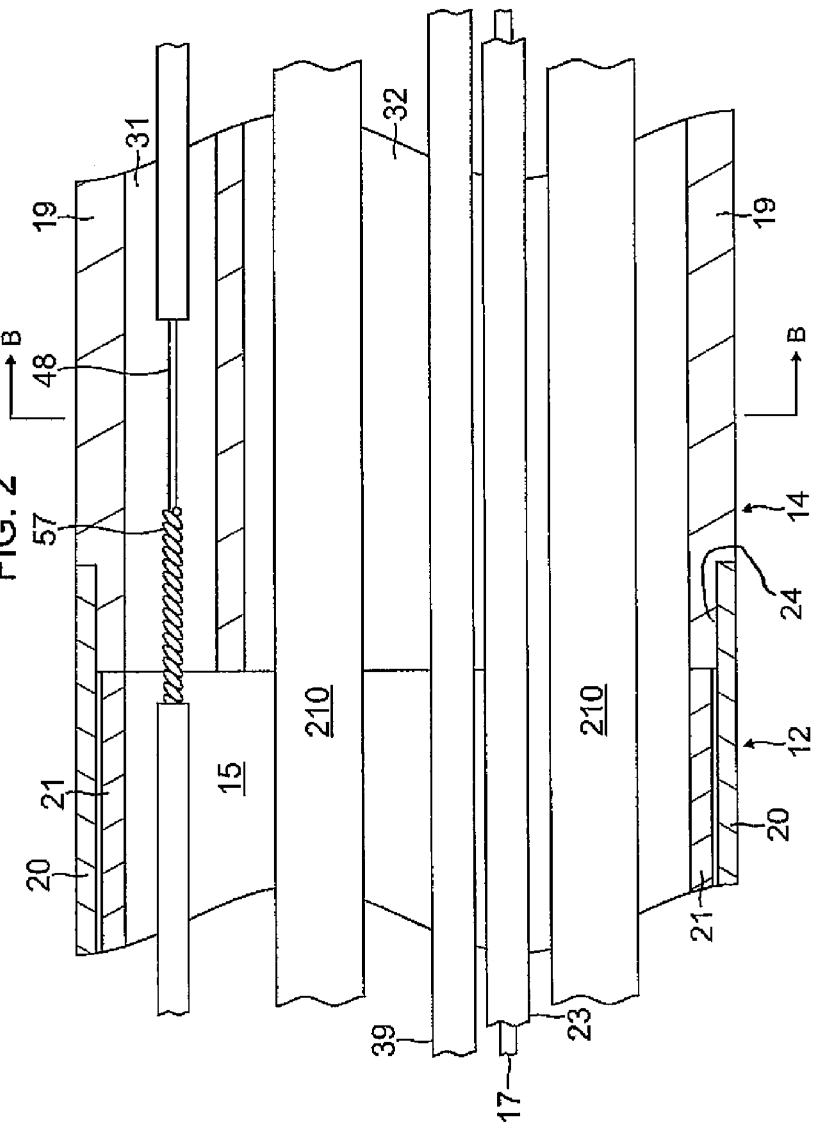

31
32
19
19
B
B
48
57
14
24
210
210
15
12
21
21
20
20
39
23
17

FIG. 3A

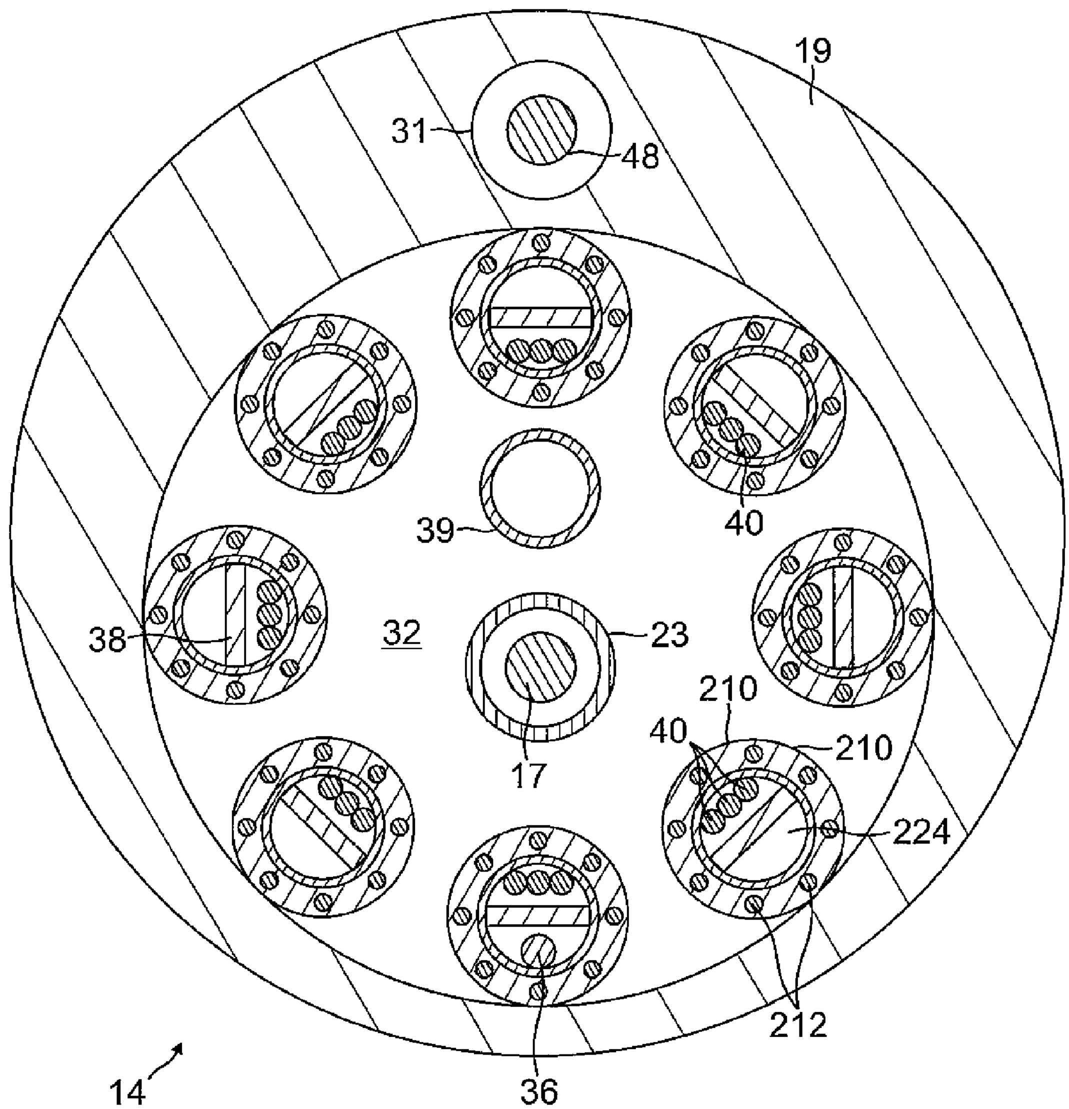


FIG. 3B

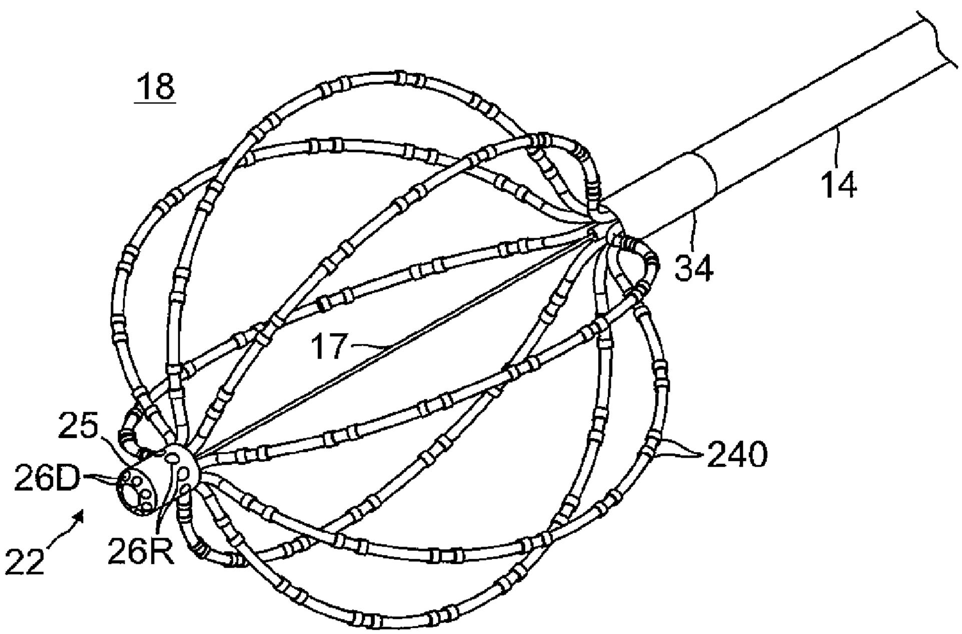


FIG. 4A

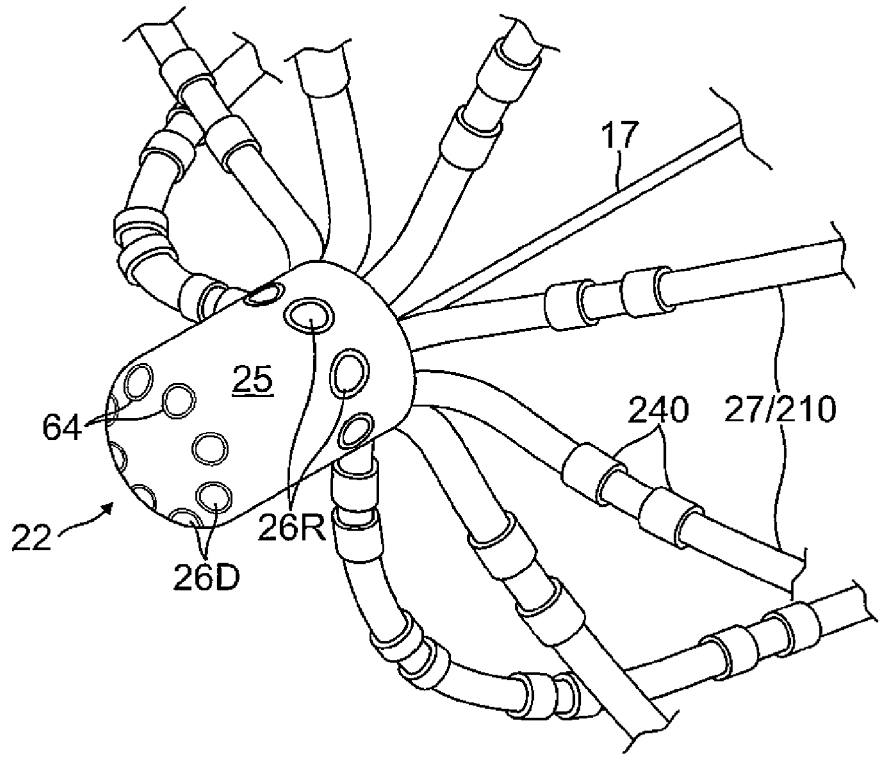


FIG. 4B

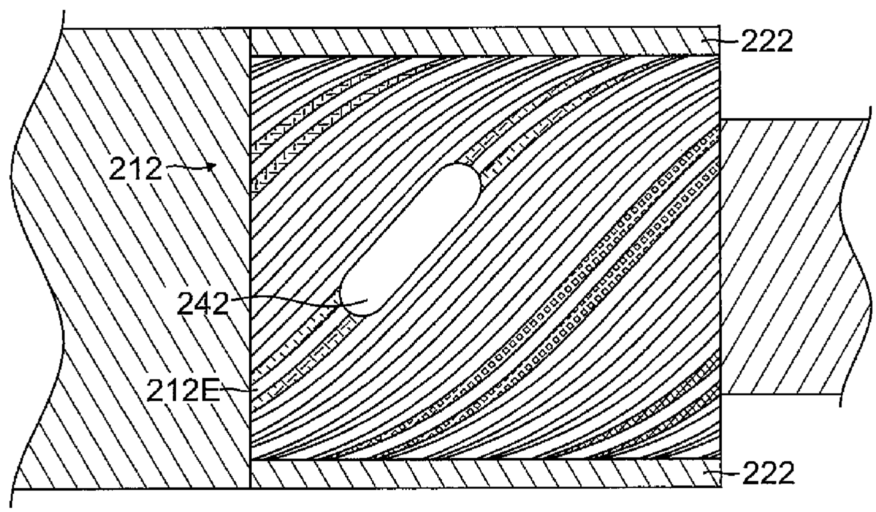


FIG. 5A

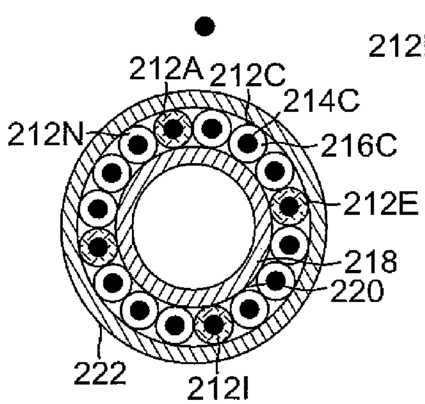


FIG. 5B

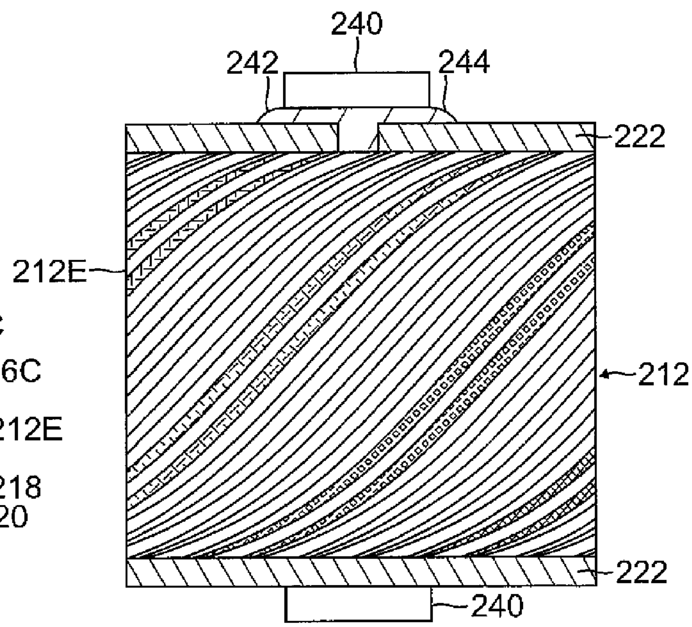


FIG. 5C

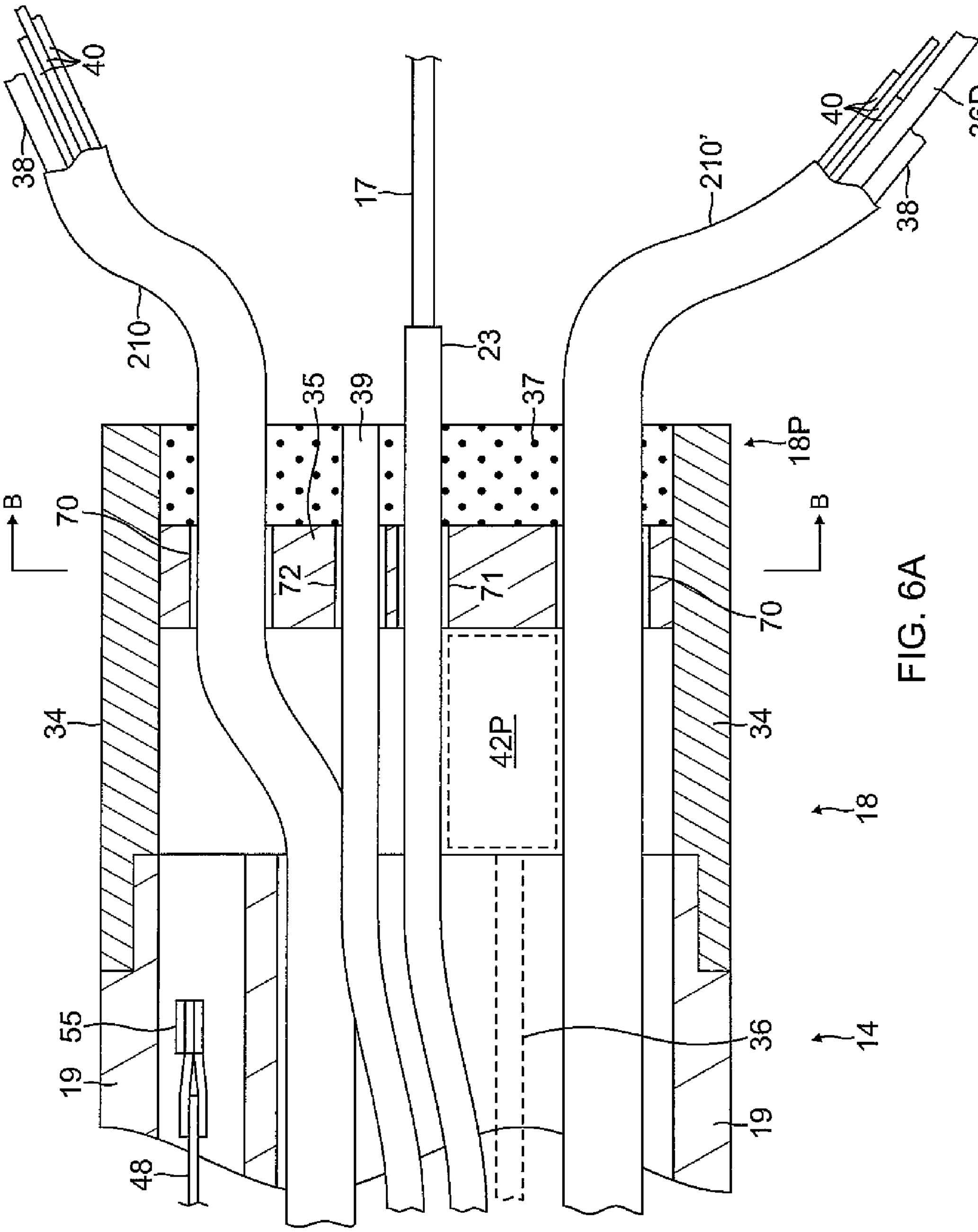
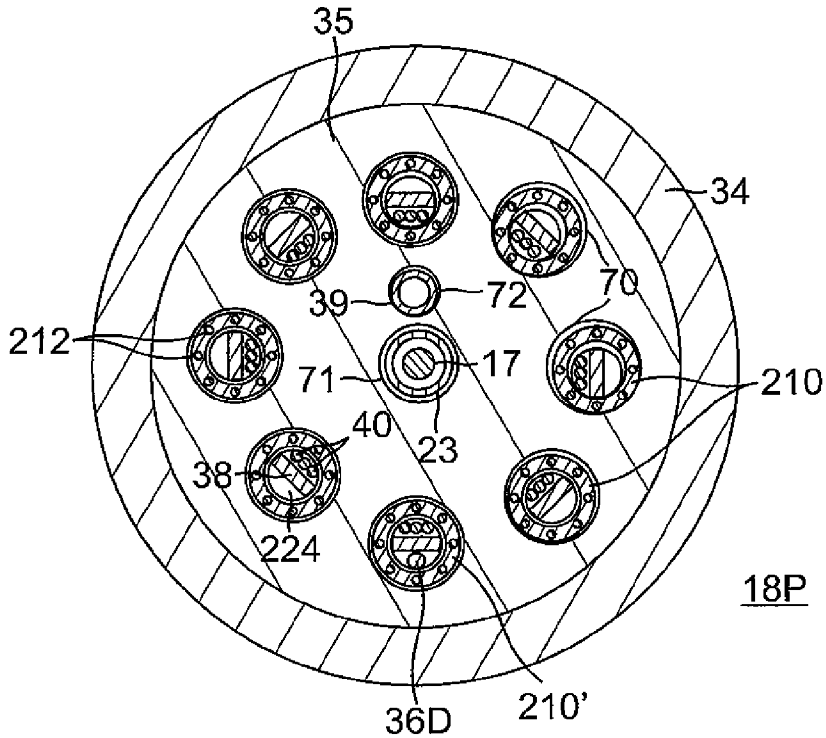

40
38
210
17
23
35
39
37
18P
B
70
72
71
34
42P
18
14
55
36
19
48
40
36D
210'
38

FIG. 6A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210
40
23
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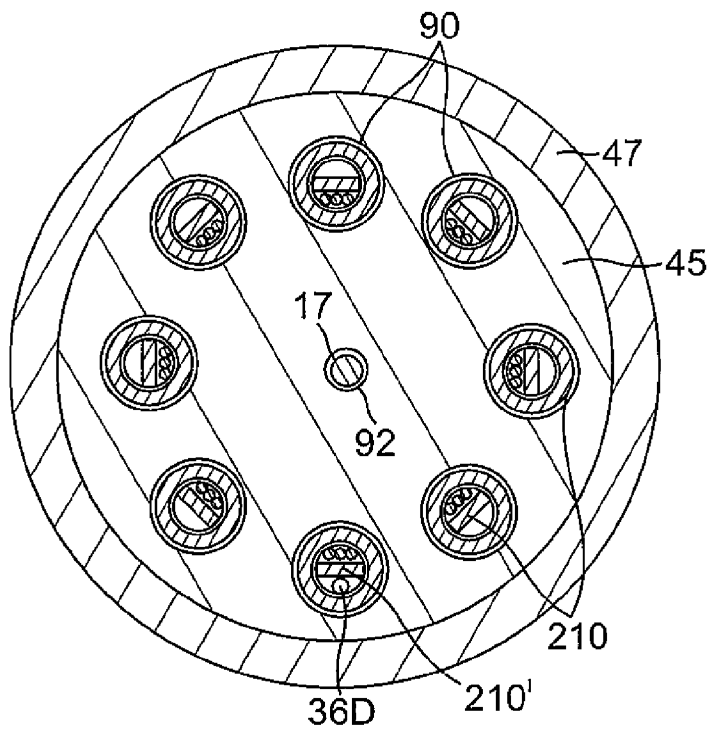
18P
36D
210'

FIG. 6B


90
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17
92
210
36D
210'

FIG. 7B

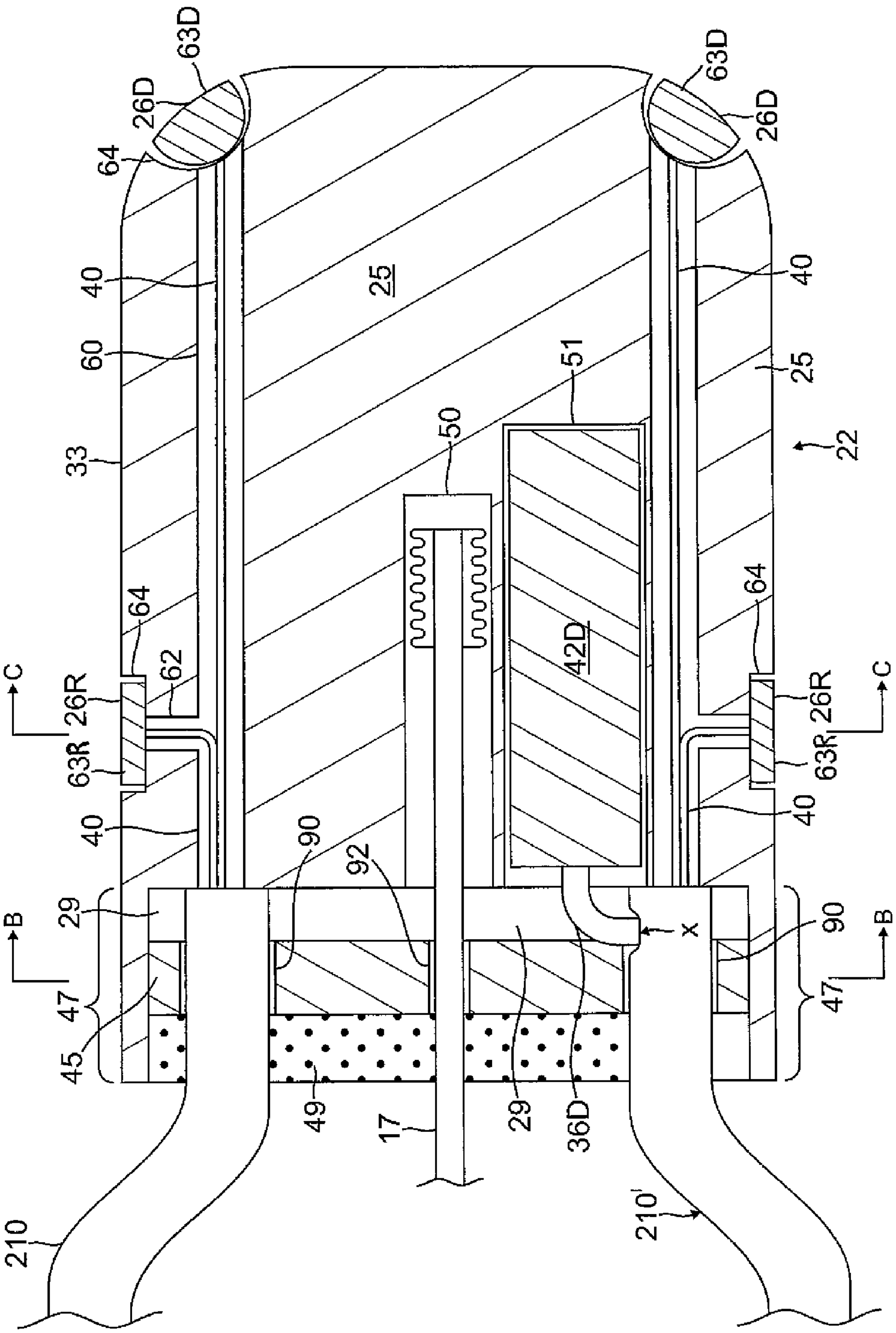
63D
26D
64
40
60
33
25
51
50
22
42D
62
26R
63R
C
40
90
92
B
29
47
45
49
17
36D
X
210
210'

FIG. 7A

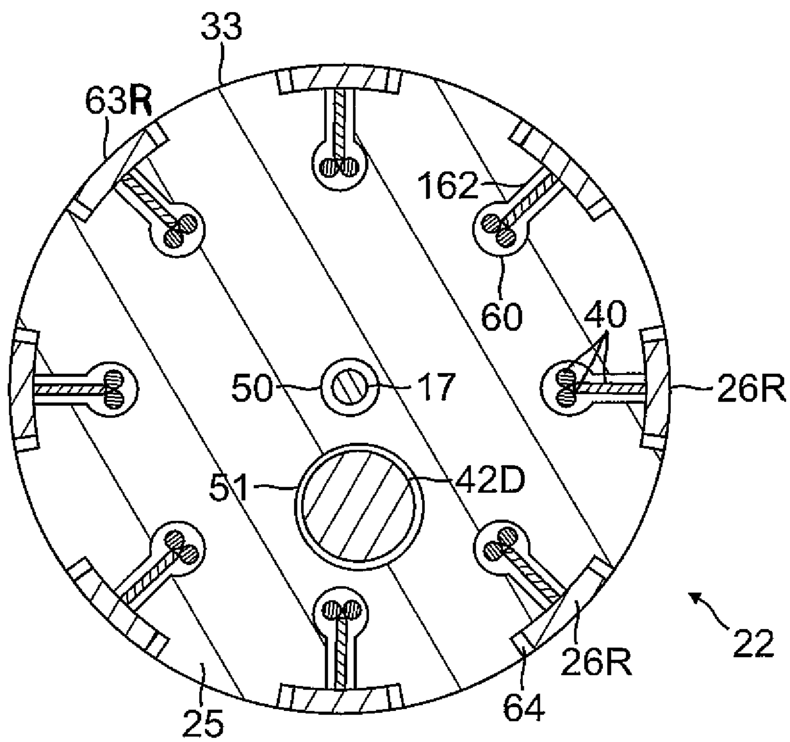

FIG. 7C

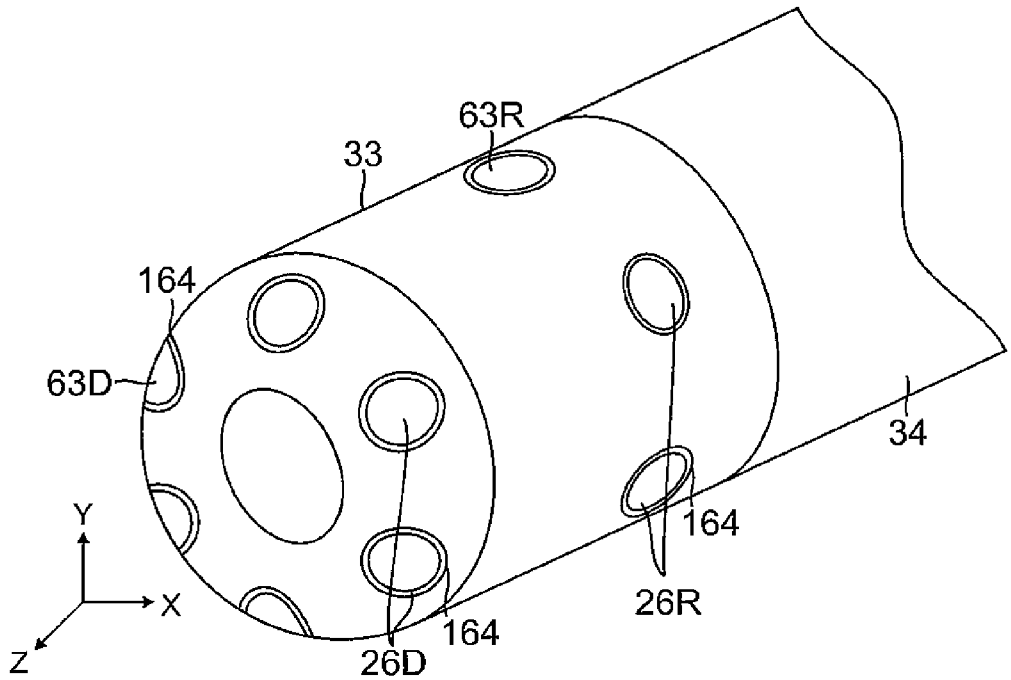
63R
33
164
63D
34
Y
X
Z
164
26R
164
26D

FIG. 8

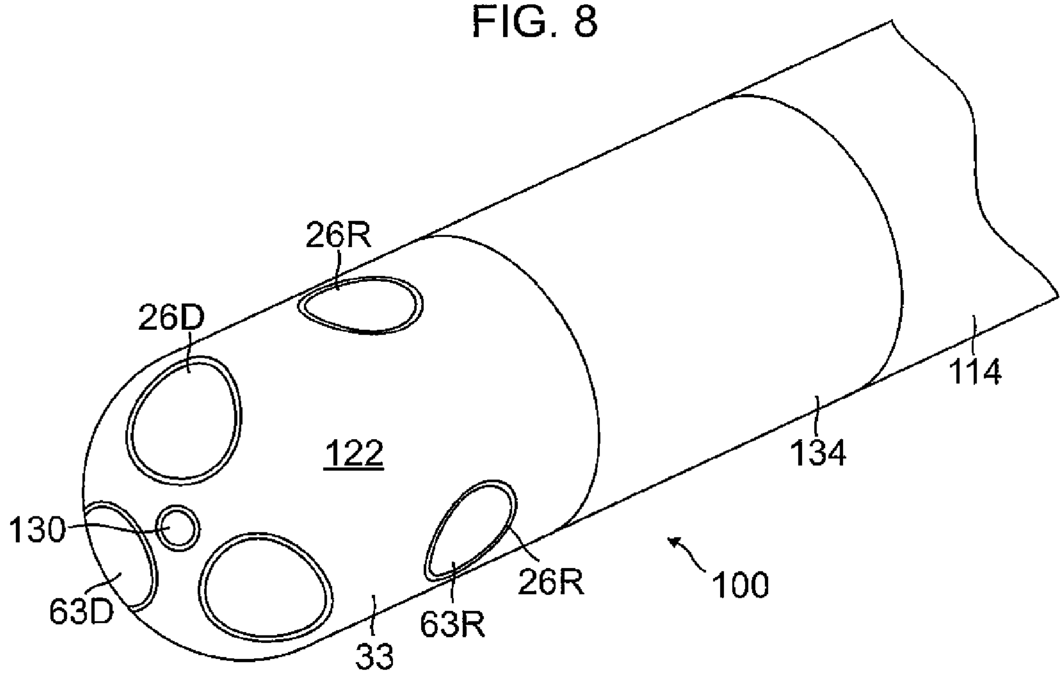
26R
26D
114
122
134
130
100
26R
63D
33
63R

FIG. 9

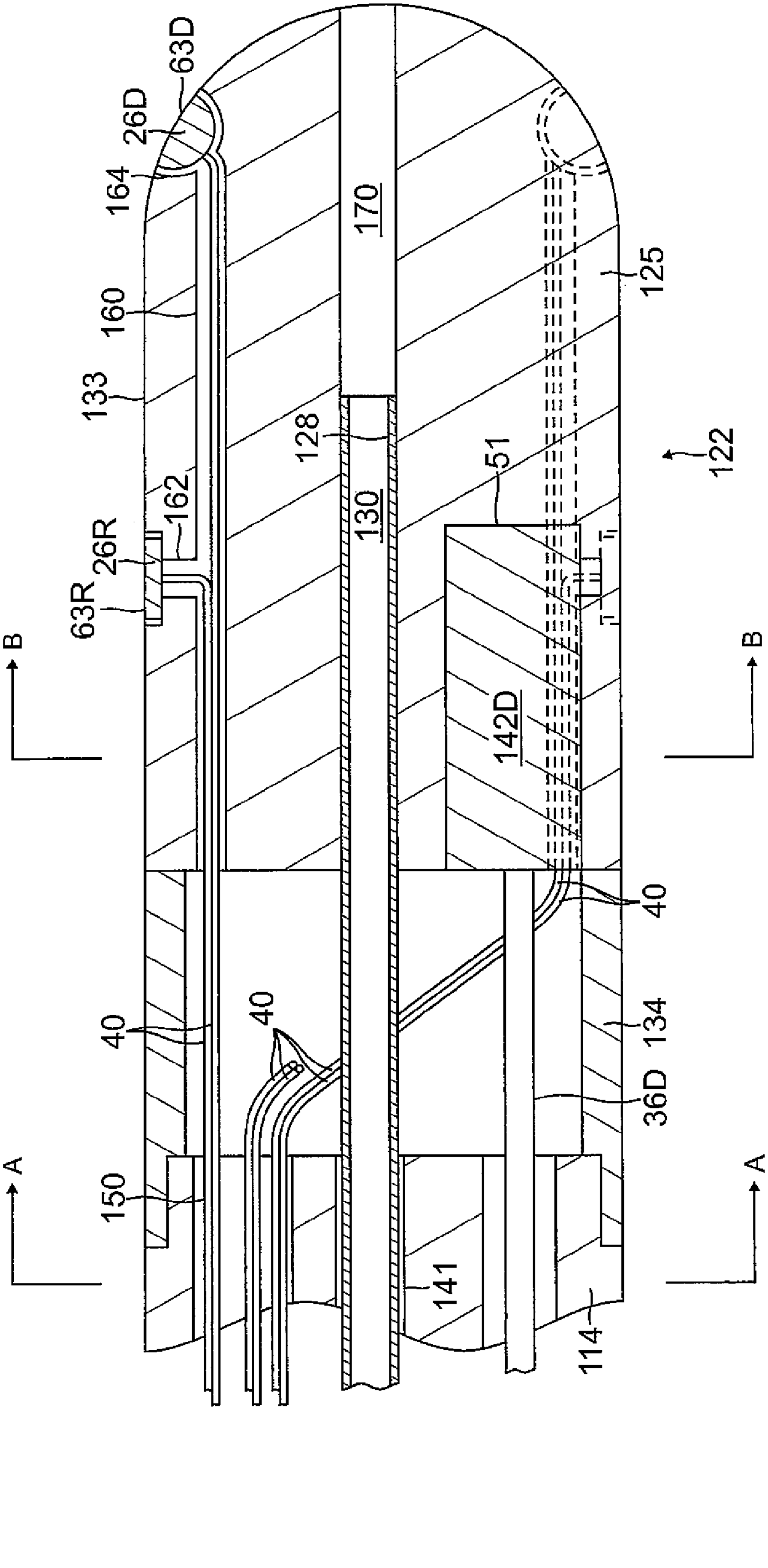
63D
26D
164
160
133
170
125
128
122
51
162
26R
63R
B
B
130
142D
40
40
40
134
36D
150
A
A
141
114

FIG. 10

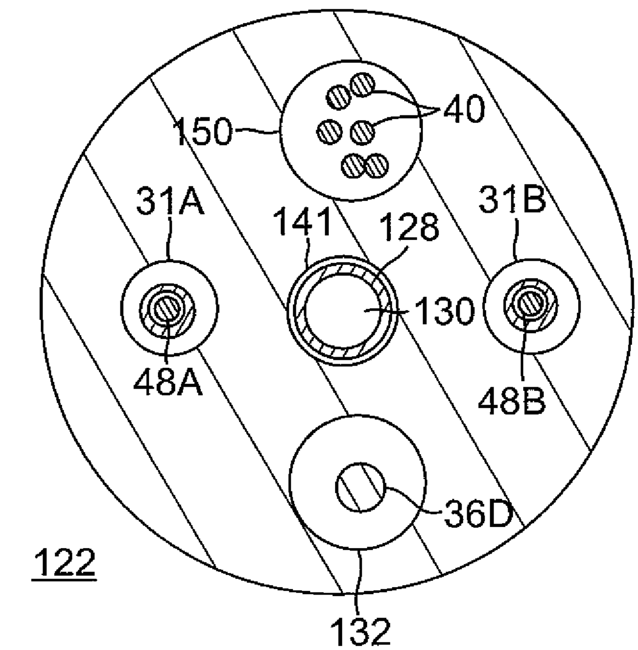

FIG. 10A

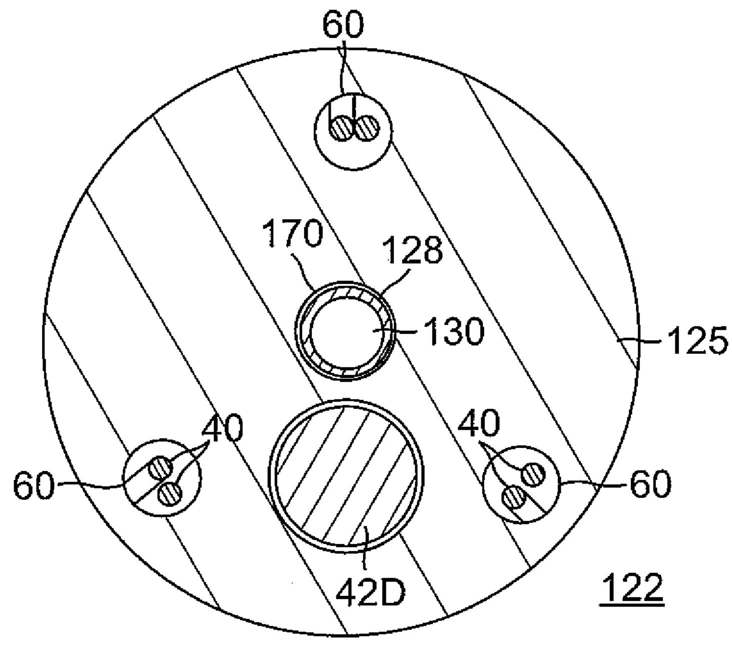

FIG. 10B

BASKET CATHETER WITH MICROELECTRODE ARRAY DISTAL TIP

FIELD OF INVENTION

This invention relates to electrophysiologic (EP) catheters, in particular, EP catheters for mapping and/or ablation in the heart.

BACKGROUND

Electrophysiology catheters are commonly-used for mapping electrical activity in the heart. Various electrode designs are known for different purposes. In particular, catheters having basket-shaped electrode arrays are known and described, for example, in U.S. Pat. Nos. 5,772,590, 6,748,255 and 6,973,340, the entire disclosures of both of which are incorporated herein by reference.

Basket catheters typically have an elongated catheter body and a basket-shaped electrode assembly mounted at the distal end of the catheter body. The basket assembly has proximal and distal ends and comprises a plurality of spines connected at their proximal and distal ends. Each spine comprises at least one electrode. The basket assembly has an expanded arrangement wherein the spines bow radially outwardly and a collapsed arrangement wherein the spines are arranged generally along the axis of the catheter body. The catheter may further comprise a distal location sensor mounted at or near the distal end of the basket-shaped electrode assembly and a proximal location sensor mounted at or near the proximal end of the basket-shaped electrode assembly. In use, the coordinates of the distal location sensor relative to those of the proximal sensor can be determined and taken together with known information pertaining to the curvature of the spines of the basket-shaped mapping assembly to find the positions of the at least one electrode of each spine.

A basket assembly is capable of detecting in a single beat most or all of the electrical function of the left or right atrium. However, because the atria of an individual patient may vary in size and shape, it is desirable that the basket assembly be sufficiently versatile and steerable to conform to the particular atrium. A basket catheter with a deflectable basket assembly for improved maneuverability to provide better tissue contact, especially in a cavernous region of the heart, including an atrium, is described in U.S. application Ser. No. 14/028,435, filed Sep. 16, 2013, the entire disclosure of which is hereby incorporated by reference.

High-density microelectrodes are also desirable for providing greater sensitivity in detecting more subtle electrical activity of heart tissue in diagnosing arrhythmias. By having a large number of electrodes often in a basket formation with spines of spaced ring electrodes, a physician can more quickly map a large area of the heart's interior geometry. Focal catheters, although lacking the resolution of a basket catheter with many electrodes, can be advantageous because their electrode location is fixed relative to the catheter distal tip.

Accordingly, it is also desirable that a basket catheter provide high-density mapping augmented with a focal diagnostic catheter tip with precisely known microelectrode locations, especially where the focal tip electrode is populated with an array of microelectrodes, in a focal catheter dimensional envelope, or even smaller, such as within a guidewire range.

SUMMARY OF THE INVENTION

The present invention is directed to a basket catheter having an ultra high density microelectrode distal tip electrode comprising a non-metallic electrically insulating structure that is populated with a collection of tiny, closely spaced electrodes formed from, for example, a medical grade metal, such as palladium, platinum, gold, stainless steel and the like, and combinations thereof. The distal tip electrode may be irrigated and fitted with a location sensor. The catheter of the present invention allows for the microelectrode distal tip electrode to be deployed in a number of microelectrode configurations, and a variety of embodiments. The ultra high density microelectrode distal tip electrode may be integrated with a high density basket catheter or a standalone focal catheter, or made smaller to fit the tip of a guidewire.

The present invention is directed to a catheter having an elongated catheter body and a basket electrode assembly at the distal end of the catheter body, where the basket electrode assembly has a plurality of electrode-carrying spines and a distal end comprising a substrate body with a plurality of recessed microelectrodes. The substrate body has an outer surface and outer surfaces of the recessed microelectrodes are advantageously flush with the outer surface of the substrate body, so that the distal end presents a completely smooth and atraumatic profile.

In one embodiment, the distal end substrate body has a proximal portion with a radial outer surface and a distal portion with a domed outer surface. At least one radial microelectrode has an outer surface in conformity with the radial outer surface of the substrate body and at least one distal microelectrode has an outer surface in conformity with the domed outer surface of the substrate body. The outer surface of the substrate body is formed, with indentations in which the microelectrodes are nested in a manner such that only its outer (or outer-facing) surface is exposed and even with the outer surface of the substrate body. In a more detailed embodiment, the each microelectrode has a surface area ranging between about 0.05 mm^2 and 0.5 mm^2, and preferably about 0.15 mm^2. The substrate body may carry a plurality of microelectrodes ranging between about two and 20, preferably between about six and 16. Moreover, lead wires connected to the microelectrodes are passed through radial and distal passages formed in the substrate body.

The present invention is also directed to a focal catheter having an elongated catheter body and a distal tip with a substrate body and a plurality of recessed microelectrodes, whose outer surface is flush with the outer surface of the substrate body. The distal tip of the focal catheter has all the aforementioned structural advantages for greater mapping resolution and greater location precision.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. **1** is a top plan view of a catheter of the present invention, according to one embodiment, with a basket electrode assembly in an expanded, deployed configuration.

FIG. **2** is a detailed view of the basket electrode assembly of FIG. **1**, in a collapsed configuration.

FIG. **3**A is a side cross-sectional view of the catheter of the present invention, including a junction between a catheter body and a deflection section, along a diameter.

FIG. **3**B is an end cross-sectional view of the deflection section of FIG. **3**A, taken along line B-B.

FIG. **4**A is a detailed view of the basket electrode assembly of FIG. **1**, in an expanded, deployed configuration.

FIG. **4**B is a detailed view of a distal end of the basket electrode assembly of FIG. **4**A.

FIG. **5**A is a top view of a cabling for use with the present invention, according to one embodiment, with part(s) broken away.

FIG. **5**B is an end cross-sectional view of the cabling of FIG. **5**A.

FIG. **5**C is a side view of the cabling of FIG. **5**A, with part(s) broken away.

FIG. **6**A is a side cross-sectional view of a proximal junction of the basket electrode assembly, according to one embodiment.

FIG. **6**B is an end cross-section view of the proximal junction of FIG. **6**A, taken along line B-B.

FIG. **7**A is a side cross-sectional view of a distal tip, in accordance with one embodiment.

FIG. **7**B is an end cross-sectional view of the distal tip of FIG. **7**A, taken along line B-B.

FIG. **7**C is an end cross-sectional view of the distal tip of FIG. **7**A, taken along line C-C.

FIG. **8** is a detailed perspective view of a distal tip of a focal catheter, in accordance with one embodiment.

FIG. **9** is a detailed perspective view of a distal tip of a focal catheter with a guidewire passage, in accordance with one embodiment.

FIG. **10** is a side cross-sectional view of the distal tip of FIG. **9**.

FIG. **10**A is an end cross-sectional view of the distal tip of FIG. **10**, taken along line A-A.

FIG. **10**B is an end cross-sectional view of the distal tip of FIG. **10**, taken along line B-B.

DETAILED DESCRIPTION OF THE INVENTION

The invention is directed to a catheter **10** having a basket-shaped, high density electrode assembly **18** for large-area mapping, with an integrated distal tip **22** providing an array of ultra high density microelectrodes for acute focal mapping. As shown in FIG. **1**, the catheter **10** comprises an elongated catheter body **12** having proximal and distal ends, a control handle **16** at the proximal end of the catheter body, an intermediate deflection section **14** distal of the catheter body **12**, and the basket-shaped electrode assembly **18** at the distal end of the deflection section **14**. The basket-shaped electrode assembly (or "basket assembly") **18** has a plurality of spines **27** whose proximal ends and distal ends surround an elongated expander **17** that is afforded longitudinal movement relative to the catheter for adjusting the shape of the basket assembly between an expanded configuration (FIG. **1**) and a collapsed configuration (FIG. **2**). Mounted on the distal end of the basket assembly **18** is the distal tip **22** having a plurality of surface-embedded microelectrodes **26** whose outer surface is generally flush with the outer surface of the substrate body to present a generally smooth, atraumatic distal tip profile.

With reference to FIG. **3**A, the catheter body **12** comprises an elongated tubular construction having a single, axial or central lumen **15**, but can optionally have multiple lumens if desired. The catheter body **12** is flexible, i.e., bendable, but substantially non-compressible along its length. The catheter body **12** can be of any suitable construction and made of any suitable material. One construction comprises an outer wall **20** made of polyurethane or PEBAX® (polyether block amide). The outer wall **20** comprises an imbedded braided mesh of stainless steel or the like to increase torsional stiffness of the catheter body **12** so that, when the control handle **16** is rotated, the distal end of the catheter body will rotate in a corresponding manner.

The outer diameter of the catheter body **12** is not critical, but may be no more than about 8 french, more preferably 7 french. Likewise the thickness of the outer wall is not critical, but is preferably thin enough so that the central lumen **15** can accommodate a puller wire, lead wires, sensor cable and any other wires, cables or tubes. If desired, the inner surface of the outer wall is lined with a stiffening tube **21** to provide improved torsional stability. An example of a catheter body construction suitable for use in connection with the present invention is described and depicted in U.S. Pat. No. 6,064, 905, the entire disclosure of which is incorporated herein by reference.

Distal of the catheter body **12** is the intermediate deflection section **14** which comprises a multi-lumened tubing **19**, with, for example, at least two off axis lumens **31** and **32**, as shown in FIGS. **3**A and **3**B. The multi-lumened tubing **19** is made of a suitable non-toxic material that is preferably more flexible than the catheter body **12**. In one embodiment, the material for the tubing **19** is braided polyurethane or thermoplastic elastomer (TPE), for example, polyether block amide (PEBAX®), with an imbedded mesh of braided high-strength steel, stainless steel or the like. The outer diameter of the deflection section **14** is no greater than that of the catheter body **12**. In one embodiment, the outer diameter is no greater than about 8 french, more preferably about 7 french. Larger or smaller embodiments are possible, as determined by the number of spines in the basket, if applicable. The size of the lumens is not critical, so long as the lumens can accommodate the components extending therethrough.

A means for attaching the catheter body **12** to the deflection section **14** is illustrated in FIG. **3**A. The proximal end of the deflection section **14** comprises an outer circumferential notch **24** that receives the inner surface of the outer wall **20** of the catheter body **12**. The deflection section **14** and catheter body **12** are attached by adhesive (e.g. polyurethane glue) or the like. Before the deflection section **14** and catheter body **12** are attached, however, the stiffening tube **21** is inserted into the catheter body **12**. The distal end of the stiffening tube **21** is fixedly attached near the distal end of the catheter body **12** by forming a glue joint (not shown) with polyurethane glue or the like. Preferably, a small distance, e.g., about 3 mm, is provided between the distal end of the catheter body **12** and the distal end of the stiffening tube **21** to permit room for the catheter body **12** to receive the notch **24** of the deflection section **14**. A force is applied to the proximal end of the stiffening tube **21**, and, while the stiffening tube **21** is under compression, a first glue joint (not shown) is made between the stiffening tube **21** and the outer wall **20** by a fast drying glue, e.g. Super Glue®. Thereafter, a second glue joint (not shown) is formed between the proximal ends of the stiffening tube **21** and outer wall **20** using a slower drying but stronger glue, e.g. polyurethane.

The basket-shaped electrode assembly **18** is mounted to the distal end of the catheter body **12**. As shown in FIGS. **1** and **4**A, the basket-shaped electrode assembly **18** comprises a plurality of electrode-carrying spines **27** or arms (e.g., between about five to ten, and preferably about eight) mounted, generally evenly-spaced in about 360 radial degrees around the expander **17** so that the expander forms the center longitudinal axis of the electrode assembly. Each of the spines **27** is attached, directly or indirectly, at its distal end to the distal end of the expander **17**. As actuated by longitudinal movement of the expander **17** relative to the catheter, the basket assembly **18** is adapted to assume an elongated and collapsed configuration with the expander **17** extended distally (FIG. **2**) and a deployed and radially expanded configuration with the expander drawn proximally (FIG. **1**). The expander **17** comprises a material sufficiently rigid to achieve this function. In an embodiment, the expander **17** is a wire or tensile member, and a guide tube **23** is provided to surround, protect and guide the expander **17** through the control handle **16**, the catheter body **12** and the deflection section **14**. The guide tube **23** is made of any suitable material, including polyimide.

In one embodiment, each spine **27** of the basket assembly **18** comprises a cabling **210** with build-in or embedded lead wires **212**, as shown in FIGS. **5**A, **5**B and **5**C. The cabling has a core **218**, and a plurality of generally similar wires **212** covered by an insulating layer **216** that enables each wire to be formed and to function as a conductor **214**. The core **218** provides a lumen **224** in which can pass other components such as additional lead wire(s), cables, tubing and/or a support structure to shape the cabling as desired.

In the following description, generally similar components associated with cabling **210** are referred to generically by their identifying component numeral, and are differentiated from each other, as necessary, by appending a letter A, B, . . . to the numeral. Thus, wire **212**C is formed as conductor **214**C covered by insulating layer **216**C. While embodiments of the cabling may be implemented with substantially any plurality of wires **212** in the cabling, for clarity and simplicity in the following description cabling **210** is assumed to comprise N wires **212**A, **212**B, **212**C, . . . **212**N, where N equals at least the number of ring electrodes on each respective spine of the basket assembly **18**. For purposes of illustration, insulating layers **216** of wires **212** have been drawn as having approximately the same dimensions as conductors **214**. In practice, the insulating layer is typically approximately one-tenth the diameter of the wire.

The wires **212** are formed over an internal core **218**, which is typically shaped as a cylindrical tube, and core **218** is also referred to herein as tube **218**. The core material is typically selected to be a thermoplastic elastomer such as a polyether block amid (PEBA) or PEBAX® Wires **212** are formed on an outer surface **220** of the core **218** by coiling the wires around the tube **218**. In coiling wires **212** on the surface **220**, the wires are arranged so that they contact each other in a "close-packed" configuration. Thus, in the case that core **218** is cylindrical, each wire **212** on the outer surface is in the form of a helical coil. In the case of the tube **218** being cylindrical, the close packed arrangement of the helical coils of wires **212** means that the wires are configured in a multi-start thread configuration. Thus, in the case of the N wires **212** assumed herein, wires **212** are arranged in an N-start thread configuration around cylindrical tube **218**.

In contrast to a braid, all helical coils of wires **212** herein have the same handedness (direction of coiling). Moreover, wires in braids surrounding a cylinder are interleaved, so are not in the form of helices. Because of the non-helical nature of the wires in braids, even braid wires with the same handedness do not have a threaded form, let alone a multi-start thread configuration. Furthermore, because of the lack of interleaving in arrangements of wires in embodiments of the cabling, the overall diameter of the cabling produced is less than that of cabling using a braid, and the reduced diameter is particularly beneficial when the cabling is used for a catheter.

Once wires **212** have been formed in the multi-start thread configuration described above, the wires are covered with a protective sheath **222**. The protective sheath material is typically selected to be a thermoplastic elastomer such as PEBA, for example, 55D PEBAX without additives so that it is transparent. In that regard, insulating layer of at least one of wires **212** is colored differently from the colors of the remaining wires as an aid in identifying and distinguishing the different wires.

The process of coiling wires **212** around the core **218**, and then covering the wires by the sheath **222** essentially embeds the wires within a wall of cabling **210**, the wall comprising the core and the sheath. Embedding the wires within a wall means that the wires are not subject to mechanical damage when the cabling is used to form a catheter. Mechanical damage is prevalent for small wires, such as 48AWG wires, if the wires are left loose during assembly of a catheter.

In use as a catheter, an approximately cylindrical volume or lumen **224** enclosed by the core **218**, that is afforded by embedding smaller wires (such as the 48 AWG wires) in the wall, allows at least a portion of the lumen **224** to be used for other components. It is understood that the plurality of wires **212** shown in the drawings is representative only and that a suitable cabling provides at least a plurality of wires equal to or greater than the plurality of ring electrodes mounted on each cabling or spine of the basket assembly. Cabling suitable for use with the present invention is described in U.S. application Ser. No. 13/860,921, filed Apr. 11, 2013, entitled HIGH DENSITY ELECTRODE STRUCTURE, and U.S. application Ser. No. 14/063,477, filed Oct. 25, 2013, entitled CONNECTION OF ELECTRODES TO WIRES COILED ON A CORE, the entire disclosures of which are incorporated herein by reference. Each cabling **210** (with embedded lead wires **212**) extends from the control handle **16**, through the lumen **15** of the catheter body **12**, and the larger lumen **32** of the tubing **19** of the deflection section **14**, as shown in FIG. **3**A.

With reference to FIGS. **6**A and **6**B, at the proximal end of the basket assembly **18**, the cabling **210** (serving as the spines **27** of the basket assembly **18**, and used interchangeably herein) extend through a proximal junction **18**P that includes an outer tubing **34** that extends a short distance from the distal end of the tubing **19** of the deflection section **14**. The outer tubing **34** may be made of any suitable material, for example, PEEK (polyetheretherketone).

In the lumen of the outer tubing **34**, a proximal alignment disc **35** formed with a plurality of through-holes is provided to receive and position the cabling **210** and the guide tube **23** of the expander **17** in the outer tubing **34**. The proximal disc **35** is made of any suitable material, including metal or plastic. In the embodiment of FIGS. **6**A and **6**B, the proximal disc **35** has an on-axis through-hole **71** for the guide tube **23**, and a plurality of off-axis through-holes **70** around a peripheral region of the disc, with each through-hole guiding a respective cabling **210** (only two of which are shown in FIG. **6**A for clarity). For example, with eight cabling **210**, the through-holes **70** are situated at about 45 radial degrees around the peripheral region. Where irrigation is desired, the disc **35** includes another off-axis through-hole **72** which receives a distal end of an irrigation tubing **39** from which fluid passing through the tubing **39** exits the catheter. Distal of the disc **35**, the lumen of the outer tubing **34** is filled and sealed with a suitable glue **37**, for example, epoxy.

The cabling **210** and the expander **17** extend distally from the proximal junction **18**P to form the basket assembly **18**. Each cabling has a predetermined shape flexibly set by a shape memory member **38** that extends through the lumen **224** in the core **218**. As shown in FIG. **3**B, selected or all of the lumens **224** of the cores **218** also carry additional lead wires **40** for the array of microelectrodes **26** on the distal tip **22**. Selected lumens **224** may also carry cable(s) **36** for electromagnetic location sensor(s) carried in the distal tip **22**.

In forming the basket shape, the shape memory members **38** in the cabling **210** diverge from the proximal junction **18**P and bow outwardly from the expander **17**, and converge at their distal ends at the distal tip **22**, as shown in FIG. **4**A. The shape memory member **38**, e.g., a Nitinol shape member or wire, is configured to flexibly provide the shape of the basket-assembly, as known in the art. In one embodiment, the shape memory member **38** of each cabling **210** has a proximal end located near the proximal end of the deflection section **14**, and a distal end located in the distal tip **22**, although it is understood that the proximal end may be located anywhere proximally of the proximal end of the deflection section **14** along the length of the cabling **210**, as desired or appropriate.

As understood by one skilled in the art, the number of spines **27** or cabling **210** of the basket assembly **18** can vary as desired depending on the particular application, so that the basket assembly **18** has at least two spines, preferably at least three spines, and as many as eight or more spines. As used herein, the term "basket-shaped" in describing the electrode assembly **18** is not limited to the depicted configuration, but can include other designs, such as spherical or egg-shaped designs, that include a plurality of expandable arms connected, directly or indirectly, at their proximal and distal ends.

Each spine **27** or cabling **210** carries a plurality of ring electrodes **240**, which may be configured as monopolar or bipolar, as known in the art. FIGS. **5**A and **5**B are schematic diagrams illustrating attachment of a ring electrode **240** to cabling **210**, according to an embodiment. FIG. **5**A is a schematic top view of the cabling and FIG. **5**B is a schematic side view of the cabling; in both views portions of sheath **222** have been cut away to expose wires **212** of the cabling **210**, as well as to illustrate the attachment of a ring electrode **240** to the cabling **210**. FIG. **5**A illustrates cabling **210** before attachment of ring electrode **240**, and FIG. **5**B illustrates the cabling after the ring electrode has been attached. Ring electrode has dimensions enabling it to be slid over sheath **222**.

Initially a location for attaching a ring electrode **240** is selected by visually finding a colored wire, such as wire **212**E. The visual determination is possible since sheath **222** is transparent. Once the location has been selected, a section of sheath **222** above the wire and a corresponding section of insulating layer **216**E are removed to provide a passage **242** to conductor **214**E. In a disclosed embodiment, conductive cement **244** is fed into the passage, ring electrode **240** is slid to contact the cement, and the electrode is then crimped in place. Alternatively, the ring electrode **240** may be attached to a specific wire by pulling the wire through sheath **222**, and resistance welding or soldering the ring electrode to the wire.

With reference to FIGS. **4**B, **7**A and **7**B, at the distal end of the basket assembly **18**, the distal ends of the cabling **210** converge around the distal end of the expander **17** in the distal tip **22**. The distal tip **22** has a generally solid, elongated, nonmetallic, electrically-insulating substrate body **25** with a generally cylindrical shape (with a two-dimensional curvature in the X/Y direction and a linear length in the Z direction), and a domed distal end (with a three-dimensional curvature in the X/Y/Z direction). The body has a trepanned proximal face **47** forming a cored-out proximal region **29** in which the distal ends of the cabling **210** and the expander **17** are received, anchored and sealed by glue **49**, for example, epoxy. A first, on-axis blind hole **50** extends distally from the cored-out proximal region to receive a crimped distal tip of the expander **17**. A second, off axis blind hole **52** extends distally from the cored-out proximal region **29** to receive at least a portion of the electromagnetic location sensor **42**.

The distal ends of the cabling **210** in the cored-out proximal region **29** are positioned by a distal alignment disc **45**. The disc **45** has a plurality of through-holes to receive the cabling **210** and the expander **17** in the outer tubing **34**. The disc **45** is made of any suitable material, including metal or plastic. In the embodiment of FIGS. **7**A and **7**B, the distal disc **45** has an on-axis through-hole **92** for the expander **17**, and a plurality of off-axis through-holes **90** around a peripheral region of the disc, with each through-hole guiding the distal end of a respective cabling **210** (only two of which are shown in FIG. **7**A for clarity). For example, with eight cabling **210**, the through-holes **90** are situated at about 45 radial degrees around the peripheral region. Proximal of the disc **45**, the cored-out proximal region **29** is filled and sealed with a suitable glue **49**, for example, epoxy.

Also formed in the body **25** of the distal tip **22** are axial passages **60** and radial passages **62**, as shown in FIG. **7**A, providing communication between the cored-out proximal region **29** and indentations **64** formed on outer surface **33** of the body **25** where the microelectrodes **26** are located. With respective pairs of the cabling **210** and axial passages **60** axially aligned with each other in the tip **22**, the additional lead wires **40** that pass through the lumen **224** of the core **218** of the cabling **210** extend through the axial and radial passages **60** and **62** for connection to the respective microelectrodes and/or temperature sensing in the distal tip **22**. Radial microelectrodes **26**R are located on radial outer surface of the body **25**. Distal microelectrodes **26**D are located on distal outer surface of the body **25**. It is understood that the plurality of wires **40** shown in the drawings is representative only and that the plurality of wires is equal to or greater than the plurality of microelectrodes carried on the distal tip **22**. Also passing through the lumen **224** of the core **218** of one predetermined cabling **210'** is the cable **36**D for the distal EM location sensor **42**D. A portion of the wall of the cabling **210'** is removed at X so as to accommodate the cable **36**D extending from a distal EM location sensor **42**D.

In accordance with a feature of the present invention, the indentations **64** are shaped and sized in correspondence with the shape and size of the microelectrode **26** which has a body that is fully received in a respective indentation **64** such that only an outer or outer-facing surface **63** of the microelectrode is exposed and generally even and flush with the outer surface **33** of the body **25** of the distal tip **22**, as shown in FIGS. **7**A and **7**C. The indentations **64** allow the microelectrodes **26** to be recessed in the body **25** to provide a smooth and atraumatic profile which minimizes the risk of the microelectrodes snagging, scratching or otherwise damaging tissue in contact with the distal tip **22**. Each indentation minimizes, if not prevents, contact between tissue and a microelectrode except by the outer surface **63** of the microelectrode. The indentation limits tissue contact by any side surface or inner surface of a microelectrode by surrounding the microelectrode except for the outer surface.

Moreover, the outer surface **63** of the microelectrode **26** has the same contour as the surrounding outer surface **33** of the substrate body **25**. For example, the distal microelectrodes **26**D have three-dimensionally curved outer surfaces **63**D that conform with the three-dimensionally curved outer surface **33** of the substrate body **25** at its distal end, and the radial microelectrodes **26**R have two-dimensionally curved outer surfaces **63**R that conform with the two-dimensionally curved outer surfaces **33** of the substrate body **25**. With a generally smooth profile, the tip **22** can be pivoted about its distal end in a circular motion where its longitudinal axis traces a cone C to improve electrode contact with minimum risk of damage to tissue, especially in a cavernous region, such as an atrium.

Each microelectrode **26** has a surface area ranging between about 0.05 mm^2 and 0.5 mm^2, and preferably 0.15 mm^2. Thus, the distal tip **22** comprises a plurality of tiny, closely spaced electrodes that may be formed from any suitable material, including medical-grade metal, for example, palladium, platinum, gold, stainless steel and the like, and combinations thereof. With a large number of microelectrodes **26**, the tip **22** advantageously provides focal diagnostic capabilities with precisely known microelectrode locations by means of their fixed location relative to the tip body **25**, whereas the basket assembly **18** with its large number of ring electrodes **240** on the spines **27** allows the physician to more quickly cover a large area of internal geometry of a cavernous region, such as the heart.

Each of the ring electrodes **240** on the spines **27** and each of the microelectrodes **26** is electrically connected via the lead wires **212** and **40**, respectively, to an appropriate mapping system and/or source of ablation energy remote from the catheter by means of a multi-pin connector (not shown) at the proximal end of the control handle **16**. The cabling **210** with embedded electrode lead wires **212** in its wall and additional lead wires **40** and EM sensor cable **36** in its lumen **224** pass from the control handle **16** and through the central lumen **15** of the catheter body **12** and the lumen **32** of the deflection section **14** and extends through the basket assembly **18** as the spines where lead wires **212** are connected to the ring electrodes, the lead wires **40** are connected to the microelectrodes **26** on the distal tip **22** and the cable **36** to the EM sensor in the distal tip **22**. By combining the basket assembly **18** with a microelectrode distal tip **22**, the catheter is adapted for both large area mapping and acute focal mapping.

The expander **17** has a suitable length that extends the entire length of the catheter. The expander includes a proximal end **17**P (FIG. **1**) that is exposed proximally of the control handle **16**, a main portion that extends through the control handle **16**, the central lumen **15** of the catheter body **12**, and the lumen **32** of the deflection section **14**, and an exposed distal portion extending through the basket assembly **18** and into the distal tip **22**. The guide tube **23** extends through the control handle **16**, the central lumen **15** of the catheter body, and the lumen **32** of the deflection section **14** and has distal end that extends a short distance distal of the distal end of the outer tubing **34** of the proximal junction **18**P of the basket assembly **18**. A user manipulates the proximal end **17**P by advancing or withdrawing the expander **17** longitudinally relative to the control handle **16** and the catheter so that it can move the distal ends of the spines **27** proximally or distally relative to the catheter to radially expand and contract, respectively, the assembly **18**.

As shown in FIGS. **3**A and **3**B, a puller wire **48** for unidirectional deflection of the deflection section **14** extends from the control handle **16** where its proximal end is anchored and responsive to a deflection knob **13** on the control handle **16**, and through the central lumen **15** of the catheter body **12** and the lumen **31** of the deflection section **14**. As shown in FIG. **6**A, a distal end of the puller wire **48** is anchored near the distal end of the deflection section **14** by a T-bar **55** as known in the art. Along the length of the lumen **15** of the catheter body **12**, the puller wire is surrounded by a compression coil **57**, as shown in FIG. **3**A. The compression coil has a proximal end at or near a junction between the control handle **16** and the catheter body **12**, and a distal end at or near the distal end of the catheter body **12**. Accordingly, when the puller wire **48** is drawn proximally by manipulation of the deflection knob **13** (FIG. **1**) on the control handle **16**, the compression coil **57** stops compression along its length so that the puller wire **48** deflects the deflection section **14** distal of the catheter body **12**. The catheter may include a second puller wire for bi-directional deflection, as known in the art.

A distal electromagnetic location sensor **42**D is connected to sensor cable **36**D that extends through the lumen **224** of selected cabling **210'** (FIG. **3**B) which extends from the catheter body **12** and control handle **16** and out the proximal end of the control handle **16** (FIG. **1**) within an umbilical cord (not shown) to a sensor control module (not shown) that houses a circuit board (not shown). Alternatively, the circuit board can be housed within the control handle **16**, for example, as described in U.S. Pat. No. 6,024,739, the disclosure of which is incorporated herein by reference. The sensor cable **36**D comprises multiple wires encased within a plastic covered sheath. In the sensor control module, the wires of the sensor cable are connected to the circuit board. The circuit board amplifies the signal received from the corresponding location sensor and transmits it to a computer in a form understandable by the computer by means of the sensor connector at the proximal end of the sensor control module. Also, because the catheter is designed for single use only, the circuit board may contain an EPROM chip that shuts down the circuit board approximately twenty-four hours after the catheter has been used. This prevents the catheter, or at least the location sensor, from being used twice.

In one embodiment, the location sensor **42**D comprises a magnetic-field-responsive coil, as described in U.S. Pat. No. 5,391,199, or a plurality of such coils, as described in International Publication WO 96/05758. The plurality of coils enables six-dimensional position and orientation coordinates to be determined. Alternatively, any suitable location sensor known in the art may be used, such as electrical, magnetic or acoustic sensors. Suitable location sensors for use with the present invention are also described, for example, in U.S. Pat. Nos. 5,558,091, 5,443,489, 5,480,422, 5,546,951, and 5,568,809, and International Publication Nos. WO 95/02995, WO 97/24983, and WO 98/29033, the disclosures of which are incorporated herein by reference. In one embodiment, an electromagnetic mapping sensor has a length of from about 3 mm to about 7 mm, preferably about 4 mm.

A proximal EM location sensor **42**P may be provided at the proximal end of the basket assembly **18**, as shown in broken lines in FIG. **6**A. The sensor **42**P is housed in the outer tubing **34** and a cable **36**P, also shown in broken lines in FIG. **6**A, for the proximal location sensor **42**P may extend through the central lumen **15** of the catheter body **12**, and the lumen **32** of the deflection section **14**. With a second location sensor, the coordinates of the distal sensor **42**D, relative to those of the proximal sensor **42**P, are determined and taken together with other known information pertaining to the curvature of the spines **27** of the basket-shaped mapping assembly **18**. This information is used to find the positions of the ring electrodes **240** mounted on the spines **26**.

As would be recognized by one skilled in the art, other arrangements for constructing the proximal and distal junctions and for mounting the location sensors could also be used in accordance with the invention.

The distal tip **22** may carry any number of microelectrodes **26**. For example, the distal tip **22** may carry 16 microelectrodes **26** (eight distal and eight radial), as shown in FIG. **8**, or it may carry six microelectrodes **26** (three distal and three radial), as shown in FIG. **9**. With reference to FIGS. **9** and **10**, a distal portion of a focal catheter **100** is shown, with a distal tip **122** that extends from a deflection section **114**. With additional reference to FIGS. **10**A and **10**B, the distal tip **122** constructed in a similar manner described above for distal tip **22**, including a nonmetallic, electrically insulating substrate body **125** and a plurality of surface-embedded radial and distal microelectrodes **26**R and **26**D whose outer surfaces **63**R and **63**D, respectively, are generally flush with outer surface **133** of the substrate body **125** to present a generally smooth, atraumatic distal tip profile. The substrate body **125** has similar axial and radial passages **160** and **162** for the lead wires and indentations **164** for the embedded microelectrodes. A distal location sensor **142**D is located in a blind hole **51** formed in the proximal end of the substrate body **125**. However, in this embodiment, the focal catheter **100** is configured with a guide wire passage **130** that extends longitudinally within the catheter from the control handle **16** to the distal tip **122**. The passage **130** is defined by the lumen of a tubing **128** that extends through the control handle, the center lumen of the catheter body, a dedicated on-axis lumen **141** in the deflection section **114**, and a connector tubing **134** connecting the deflection section **114** and the distal tip **122**. A distal end of the tubing **128** is received in a longitudinal on-axis passage **170** formed the substrate body **125** to extend the guidewire passage **130** to the distal face of the substrate body.

The focal catheter **100** may be deflected bi-directionally by means of first and second puller wires **48**A and **48**B extending through diametrically opposite, off axis lumens **31**A and **31**B formed in the tubing of the deflection section **114**.

To use the catheter **100** of the invention, an electrophysiologist introduces a dilator and a guiding sheath into the patient, as is generally known in the art. A suitable guiding sheath for use in connection with the inventive catheter is the PREFACE™ Braided Guiding Sheath (commercially available from Biosense Webster, Inc., Diamond Bar, Calif.). The catheter is introduced through the guiding sheath with the expander extended and the basket assembly collapsed so that the basket assembly can be fed into the guiding sheath. The guiding sheath covers the spines of the basket assembly in a collapsed position so that the entire catheter can be passed through the patient's vasculature to the desired location, Once the basket assembly of the catheter reaches the desired location, e.g., the left atrium, the guiding sheath is withdrawn to expose the basket assembly. The expander is drawn proximally or otherwise manipulated so that the spines flex outwardly. With the basket assembly radially expanded, the ring electrodes contact atrial tissue. Using the ring electrodes on the spines in combination with the location sensor(s), the electrophysiologist can map local activation time and/or ablate and irrigate as needed, in diagnosing and providing therapy to the patient. With the multiple electrodes on the basket assembly, the catheter enables the electrophysiologist to obtain a true anatomy of a cavernous region of the heart, including an atrium, by measuring more points than with traditional catheters, allowing him to map the region more quickly. Moreover, for focal tissue contact, the electrophysiologist can direct the distal tip with high density microelectrodes for greater location precision and greater sensitivity in detecting more subtle electrical activity of heart tissue.

The preceding description has been presented with reference to presently disclosed embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention. As understood by one of ordinary skill in the art, the drawings are not necessarily to scale and any feature(s) of an embodiment may be incorporated into any other embodiments or combined with any other feature(s) of another embodiment, as desired or needed. Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.

What is claimed is:

1. A catheter comprising:

an elongated catheter body having proximal and distal ends and at least one lumen therethrough;

a basket electrode assembly at the distal end of the catheter body, the basket electrode assembly having proximal and distal ends and comprising a plurality of spines, the plurality of spines comprising a plurality of electrodes, the distal end of the basket electrode assembly comprising a substrate body and a plurality of recessed microelectrodes, the substrate body has an outer surface and outer surfaces of the plurality of recessed microelectrodes are flush with the outer surface of the substrate body.

2. The catheter of claim **1**, wherein the substrate body has a radial outer surface, and at least one of the plurality of recessed microelectrodes is a radial microelectrode having an outer surface flush with the radial outer surface of the substrate body.

3. The catheter of claim **2**, wherein the radial outer surface of the substrate body and the outer surface of the radial microelectrode have a common curvature in at least one direction.

4. The catheter of claim **1**, wherein the substrate body has a distal end outer surface, and at least one of the plurality of recessed microelectrodes is a distal microelectrode having an outer surface flush with the distal end outer surface of the substrate body.

5. The catheter of claim **4**, wherein the distal end outer surface of the substrate body and the outer surface of the distal micro electrode have a common curvature in at least one direction.

6. The catheter of claim **1**, further comprising an expander having proximal and distal ends, the expander forming a longitudinal axis of the basket electrode assembly, wherein the plurality of spines are attached at their proximal and distal ends to the expander.

7. The catheter of claim **1**, further comprising an intermediate deflection section between the catheter body and the basket electrode assembly.

8. The catheter of claim **7**, further comprising at least one puller wire that extends through the catheter body and the intermediate deflection section, the puller wire having a distal end anchored at or near a proximal end of the intermediate deflection section.

9. The catheter of claim **8**, further comprising a control handle proximal of the catheter body, the control handle having an actuator adapted to move the at least one puller wire.

10. The catheter of claim **1**, wherein the outer surface of the substrate body has one or more indentations receiving the plurality of recessed microelectrodes.

11. The catheter of claim **10**, wherein the indentations are sized and shaped to generally cover all surfaces of the plurality of recessed microelectrodes except their outer facing surfaces.

12. A catheter comprising:

an elongated catheter body having proximal and distal ends and at least one lumen therethrough;

a basket electrode assembly at the distal end of the catheter body, the basket electrode assembly having proximal and distal ends and comprising a plurality of spines, the plurality of spines comprising a plurality of electrodes; and a distal tip at the distal end of the basket electrode assembly, the distal tip comprising a substrate body, and a plurality of recessed microelectrodes, the substrate body having an outer surface and passages,

wherein outer surfaces of the plurality of recessed microelectrodes are flush with the outer surface of the substrate body, and

wherein lead wires for the plurality of microelectrodes pass through the passages.

13. The catheter of claim **12**, wherein each of the plurality of recessed microelectrodes has a surrounding outer surface of the substrate body, and wherein the outer surface of each of the plurality of recessed micro electrodes and its surrounding outer surface of the substrate body have a common curvature.

14. The catheter of claim **12**, wherein the plurality of recessed microelectrodes includes at least one radial microelectrode and at least one distal microelectrode, and the substrate body has a radial outer surface and a distal outer surface, and wherein an outer surface of the at least one radial microelectrode and the radial outer surface of the substrate body have a first common curvature, and an outer surface of the at least one distal microelectrode and the distal outer surface of the substrate body have a second common curvature.

15. The catheter of claim **12**, wherein the substrate body comprises a nonmetallic, electrically-insulating material.

16. The catheter of claim **12**, further comprising a guidewire passage extending through at least the catheter body.

17. The catheter of claim **16**, wherein the guidewire passage extends through the distal tip.

18. The catheter of claim **12**, wherein the plurality of recessed microelectrodes comprises at least sixteen recessed microelectrodes.

19. The catheter of claim **18**, wherein the plurality of recessed microelectrodes comprises at least eight radial microelectrodes and at least eight distal microelectrodes.

20. The catheter of claim **12**, wherein the plurality of recessed microelectrodes comprises at least six microelectrodes.

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